5 K112517

SPECIAL 510(K) PREMARKET SUMMARY

SEP 2 3 2011

UltraSeal XT® hydro™

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for UltraSeal XT® hydro™.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Manager of Regulatory and International Affairs
Telephone:	(800) 552-5512 x4491, (801) 553-4491
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Date Summary Prepared:	August 16, 2011

Name of the Device

Trade Name:	UltraSeal XT® hydro™
Common Name:	Pit and Fissure Sealant and Conditioner
Regulation Number:	CFR 872.3765
Device Classification:	II
Classification Product Code:	EBC

Legally Marketed Predicate Device to Which Equivalence is Claimed

The first predicate device is: UltraTemp XT® plus (K993846). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095. The second predicate device is Embrace™ Wet Bond™ (K052281) manufactured and distributed by Pulpdent Corporation 80 Oakland Street, Watertown, Massachusetts 02472.

Description: UltraSeal XT® hydro is a 53% filled, light cure, radiopaque, methacrylate-based, thixotropic resin sealant. It is hydrophyllic and has a self-adhesive quality. UltraSeal XT® hydro™ chemistry provides the option of a visual verification for marginal retention with the use of a UV light, upon placement and at recall visits. The UV light is not included in the Ultra Seal XT® hydro™ kit.

Indications for Use: Use Ultra Seal XT® hydro™ for prophylactic sealing of pits and fissures.

Comparison Table

	UltraSeal XT® hydro™	UltraSeal XT® plus (K993846)	Pulpdent Embrace™ Wet Bond™ (K052281)
Indications For Use	Use UltraSeal XT® hydro™ for prophylactic sealing of pits and fissures	Use UltraSeal XT® plus for prophylactic sealing of pits and fissures. It may also be used for microrestorative or "initial layer" of composite restorations.	Embrace™ Wet Bond ™ Clear Sealant is a hydrophyllic, light-cured material recommended for use as a pit and fissure sealant. Embrace™ WetBond™ Clear Sealant may be used to seal small defects such as buccal pits, lingual grooves or facial surface defects. Embrace™ WetBond™ Clear Sealant may also be used as an orthodontic bracket coating. Embrace™ WetBond™ Clear Sealant hardens/cures such that the material is clear.
Delivery System	Syringe	Syringe	Syringe

Ultradent decided to reduce the claims of microrestorative or "initial layer" of composite restorations on UltraSeal XT® hydro™ as the product was specifically designed to simply be the best pit and fissure sealant on the market.

Technological Characteristics: UltraSeal XT® hydro is a 53% filled, light cure, radiopaque, methacrylate-based, thixotropic resin sealant. It is hydrophyllic and has a self-adhesive quality. UltraSeal XT® hydro™ chemistry provides the option of a visual verification for marginal retention with the use of a UV light, upon placement and at recall visits. The UV light is not included in the Ultra Seal XT® hydro™ kit.

The unique chemistry of UltraSeal XT® hydro™ has eliminated the need to use PrimaDry (K931868) manufactured by Ultradent Products Inc., 505 West 10200 South, South Jordan, Utah 84095 or any other drying products prior to resin placement to eliminate moisture.

Brief Description of Testing Performed

Detailed test reports are located in the Design Control Section of this 510(k)

Stability Testing for Shelf Life

Stability testing was conducted on UltraSeal XT® hydro™ and the results show that the product has an 18 month shelf life based on accelerated stability studies conducted in R & D. The timing of seven weeks of storage at a temperature elevated 36°C above ambient is equivalent to 84.9 weeks or 19.5 months of real time shelf life.

a. **Shear Bond** – This is the most impressive test to show that UltraSeal XT® hydro™ provides the highest adhesion to the tooth compared to both of our predicates. This adhesion is accomplished without the use of a drying agent such as PrimaDry (K931868). A high MPa value is preferred as it shows that the product will remain on the tooth, protecting it longer than a product with a lower Shear Bond Strength. This test shows that UltraSeal XT® hydro™ will bond well to the tooth creating a very successful pit and fissure sealant.
b. **Flexural Strength** – This test will show the strength of the bond during stress. A higher number than our competitors is good. The modulus side of this test shows the strength at which flexing the bond occurs. Our testing shows more "give" to it as our competitor's product tends to be "stiffer. We prefer the elasticity as it allows the product to remain on the teeth longer and "gives" with movement.
c. **Hardness** – This test shows the resiliency of the material to resist deformation. It is acceptable for us to remain higher than our competitors.

d. **Ambient Light Working Time** This test shows the time that the product will cure in ambient light. It shows working time with the product and curing time of the product. We prefer the product to set up quickly to reduce chair time for the dentist and patient.
e. **Sorption** – This test shows how much water the resin absorbs. We want low readings on this test.
f. **Uncured Film thickness** – testing bond strength at a defined thickness.
g. **Soluability**- testing whether the product degrades in solutions or saliva. Look for a low number on this test.
h. **Compressive Strength –** Measures the material's ability to not break apart under a compressive load. Prefer a higher number.
i. **Shrinkage Stress** – This test determines shrinkage over a specified period of time. This value shows the high strength adhesion of the product.
j. **Shrinkage % -** This test determines how much shrinkage will occur when the product has fully cured. We prefer a low value on shrinkage.
k. **Depth of Cure -** This test shows the light cure ability of the product.
l. **Joules Test – Setting Time –** This test shows actual joules to cure the product in 3 seconds time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
Manager, Regulatory and Global Affairs
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

SEP 23 2011

Re: K112517
Trade/Device Name: UltraSeal XT® hydro™
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: August 16, 2011
Received: August 31, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov /MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K112517

Device Name: UltraSeal XT® hydro™

Indications for Use:

Use UltraSeal XT® hydro™ for prophylactic sealing of pits and fissures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112517